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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------------|------------------|
| 09/715,909 | 11/17/2000 | Ronald D. Flannagan | 35718/204664 | 5613 |
| 29122 | 7590 | 05/14/2004 | | |
| ALSTON & BIRD LLP PIONEER HI-BRED INTERNATIONAL, INC. BANK OF AMERICA PLAZA 101 SOUTH TYRON STREET, SUITE 4000 CHARLOTTE, NC 28280-4000 | | | EXAMINER HAYES, ROBERT CLINTON | |
| | | | ART UNIT 1647 | PAPER NUMBER |

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/715,909 | FLANNAGAN ET AL. | |
| | Examiner | Art Unit | |
| | Robert C. Hayes, Ph.D. | 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-3,7,8,10-18,28-32 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,7,8,10-18,28,29,32 and 34-39 is/are rejected.
- 7) ☒ Claim(s) 30 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 2/17/04 has been entered.
2. Applicants' arguments filed 2/17/04 have been considered but were not found persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 30-31 stand objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
5. Claims 1(f)-3, 7(f)-8, 10-18 & 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

No proper antecedent basis nor conception in context with that described within the instant specification at the time of filing Applicants' invention exists for the recitation of "comprising the ligand binding site set forth as amino acids 4038-4547 of SEQ ID NO: 2". In contrast to Applicants' assertions on page 8 of the response, no such basis exists on page 17 of

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the specification. Nor does any such basis exist on page 35 of the specification, as it relates to SEQ ID NO: 2; thereby, constituting new matter.

6. Claims 1-3, 7-8, 10-18, 28-29, 32 & 34-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed, for the reason made of record in Paper NOs: 10 (mailed 2/13/02), 13 (mailed 10/18/02), 16 (mailed 4/07/03) & 21 (mailed 11/17/03), and as follows.

In contrast to Applicants' assertions on pages 8-10 of the response, the issue remains that the claims still recite "comprising" a fragment of SEQ ID NO: 2, in which these generic nucleotide sequences still merely require "comprising the ligand binding site... of SEQ ID NO: 2" (i.e., as it relates to claim 1g). As previously made of record, no allelic variants are described within the specification. Nor are any nucleic acid molecules that encompass different species of the *Lepidopteran* order/genus described (e.g., as it relates to claims 1, 28-29 & 37-38). Again, the claims still encompass undescribed molecules not limited to encoding the open reading frame depicted as SEQ ID NO: 2, nor limited to any described *Ostrinia nubilalis* receptor nucleic acid molecule. In addition, the claims encompass unknown and undescribed heterologous sequences, which include unknown and undescribed encoded "polypeptides *of interest...*" fused to polypeptides that merely "*comprise* the ligand binding site set forth as amino acids 4038-4547 of SEQ ID NO: 2", etc., which further include unknown and undescribed encoded *generic* "toxin receptors" (e.g., as it relates to claim 8). Therefore, the written description requirements

under 35 U.S.C. 112, first paragraph are still not reasonably met by the current claims; consistent with that held by the courts in *Fiers v. Revel* and *Univ. California v. Eli Lilly and Co.* previously made of record. Thus, Applicants' arguments are not persuasive for the reasons extensively made of record. See MPEP 2163.

In summary, the specification describes the sole *Lepidopteran* insect receptor nucleic acid from the species *Ostrinia nubilalis* of SEQ ID NO:1 (see page 3 of the specification). No other species of *Lepidopteran* insect receptor nucleic acids are described by which one of skill in the art could reasonably visualize what structurally constitutes this claimed genus of insect nucleic acid sequences. Thus, Applicants are clearly not in possession of the claimed genus of *Lepidopteran* insect receptor nucleic acid molecules claimed, for the reasons made of record.

7. Claims 7-8 & 33-36 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, because it remains ambiguous what metes and bounds constitute "at least one polypeptide *of interest*", and which again is a relative term that defines nothing by itself; thereby, remaining indefinite.

In contrast to Applicants' assertions on pages 10-11 of the response, the recitation of "polypeptides of interest" by itself defines nothing; thereby, still being indefinite. Moreover, as previously made of record, although Applicants are permitted to be their own lexicographer, no term may be given meaning repugnant to the usual meaning of the term (see MPEP 608.01 (o)), in regards to the breadth encompassed by any term; especially when the specification fails to specifically define the metes and bounds this term otherwise encompasses. In other words, in

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contrast to Applicants' assertions, examples of putative encoded "polypeptides of interest" constitute an opened-ended, versus closed definition of this term, where the metes and bounds, therefore, are unknown. Thus, Applicants' arguments are moot.

8. Claims 1-3, 7-8, 10-18 & 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.


The recitation of "set forth as amino acids 4038-4547 of SEQ ID NO: 2" makes no sense, because SEQ ID NO: 2 contains only 1717 amino acid residues.


9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887. The fax phone number for this Group is (703) 308-4242.


Robert C. Hayes, Ph.D.
May 5, 2004


GARY KUNZ
SUPERVISORY PATENT EXAMINER
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